UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/736,004	12/15/2003	Yi Feng Zheng	7459	2953

34500 7590 04/19/2005

DADE BEHRING INC.
LEGAL DEPARTMENT
1717 DEERFIELD ROAD
DEERFIELD, IL 60015

EXAMINER	
HAQ, SHAFIQUL	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 04/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/736,004	ZHENG ET AL.	
	Examiner	Art Unit	
	Shafiqul Haq	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-32 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-32 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 02/02/2004.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Although specific claims are cited and discussed in the rejection below, these rejections are also applicable to all other claims in which the noted problems/language occur.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 1,7,13,20, 27 and 28 recite the term "immunogenic carrier", "label" and/or "acid salts". It is not clear what "immunogenic carrier" or "label" is encompassed by the terms as immunogenic carrier may include proteins, adjuvant and other non-protein substance and label may include various labeling agent such as fluorescein, cyanine, enzymes, radioactive substance, electrophoretic tag etc. Therefore, it is unclear what immunogenic carrier or label is intended by the terms.

   Claim 1 and 7 is also indefinite as it is also not clear what is encompassed by the term "acid salts".

5. Claims 1 and 7 recite the term "protecting group". It is not clear what is encompassed by this term because "protecting group" is a general term which includes numerous groups for protection of functional groups –OH, -NH, -SH, -

COOH and –CO. Therefore, the claims are vague and indefinite for not clearly defining the protecting group.

6. With respect to claims 21, 25, 26, 29 and 30 it is not clear "antibody" used in the method is raised against compound of what formula i.e against what hapten-immunogen conjugate?

7. With respect to claims 27, 28 and 31, it is not clear what is encompassed by the term "analog".

8. With respect to claims 12 and 19, it is not clear what is encompassed by the terms "enzyme", "luminescer" and "radioisotopes" as these are generic terms and my include variety of enzymes, luminescers and radioisotopes.

9. The term "immunogenic protein" in claims 27, 28 and 32 is confusing. It is not clear whether the "immunogenic protein" conjugated with the compound is an immunogenic carrier or it itself acts as an immunogen?

Claim Rejections - 35 USC § 102

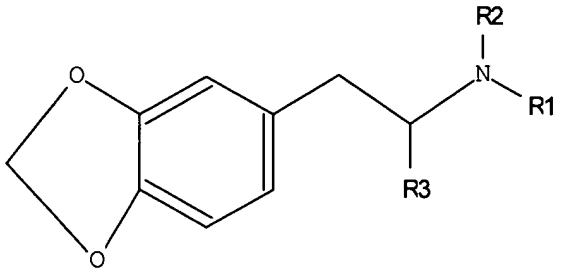
10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-24, 26, 28, 29 and 32 are rejected under 35 U.S.C. 102(a) as being anticipated by Hui et al (EP1340981 A2)).

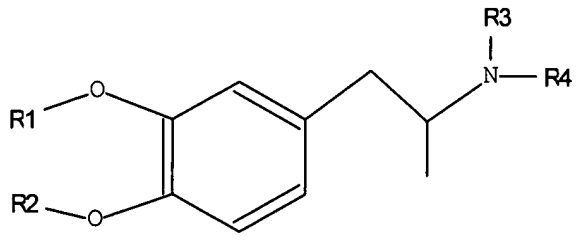
Claims recite methods, compositions and kits for detecting the presence and/or amounts of entactogens in samples.

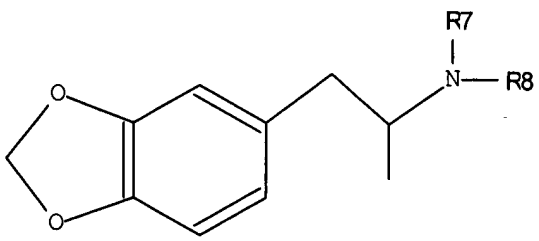
Hui et al. disclose a method for detection of 3,4- methylenedioxy-methamphetamine, immunogen/conjugate, antibody against the immunogen and a detection kit. Hui et al. disclose the following compound against which antibody is raised (paragraphs 0006-0012) :



wherein R2 and R3 = alkyl group; R1=-J-M-T wherein J=1-15 carbon atoms, M= -O-, -CO-, -NR4-, -S-,-NH(CS)-, -NHCONH-,maleimidothioether and T=macromolecular carrier or a label.

The above disclosure reads on the compounds of formula I and II (claim 1 and 7) of the instant application:





wherein R1, R2= cycle; R3, R7=alkly and R4 and R8 = as defined.

Hui et al. disclose that the functional group M may include other moieties such as carboxylic acids, amines, thioesters etc. besides the above disclosed groups (paragraph 0039, lines 27-32).

Hui et al. disclose immunogen bound to carrier (e.g. proteins, peptides) (paragraph 0035) for raising antibody against the immunogen (paragraphs 0034,0068-0073) and the antibodies show specificities to ecstasy drugs (paragraph 0054).

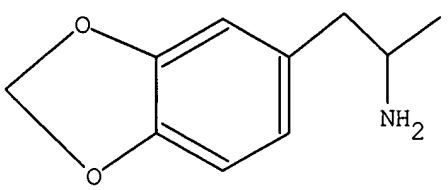
Hui et al. disclose label compounds comprising luminescent compounds, fluorescent compounds, radioactive isotopes etc. (paragraph 0022) that anticipated label compound as claimed.

Hui et al. also disclose methods/assays for detection and quantitative determination of amphetamine derivatives (paragraphs 0012, 0029, 0064-0067).

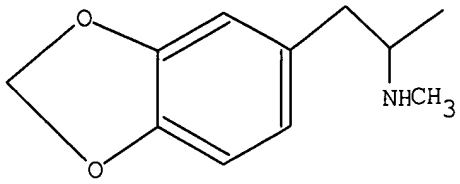
Hui et al further disclose reagent kit assembly for detection of MDMA and its methylenedioxy analogs in test samples such as biological fluids (paragraphs 0059 and 0060).

All the above disclosure reads on all the cited claims of the instant invention and therefore, the reference is deemed to anticipate the cited claims.

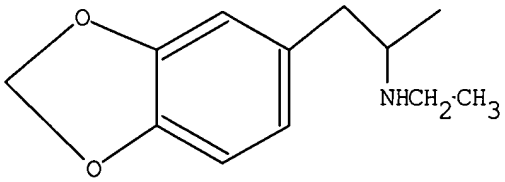
It is noted that the claimed compounds wherein R_1, R_2=cycle and R3, R4, R7, R8 =H or alkyl is anticipated by MDA, MDMA or MDEA (see Hui et al, paragraph [0002]).



MDA



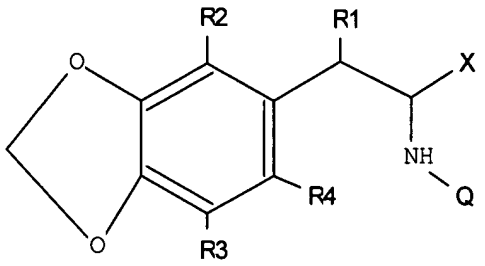
MDMA



MDEA

12. Claims 1-24, 26, 28, 29 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Rouhani et al. (GB 2361473 A).

Rouhani et al. disclose a method for detection of ecstasy-class analogs. Rouhani et al. disclose the following compound (page 11, lines 1-22; page 12, lines 1-3):



wherein R1-R4 = H; X=H or carbon atom; Q=-L'$_n$-Z, a first moiety or substituted derivative of the first moiety, wherein L'$_n$ = backbone C, N, O, S and n is >=0; first moiety is selected from a group consisting of a straight moiety or a branched moiety and has a backbone of m backbone atoms independently selected from a group

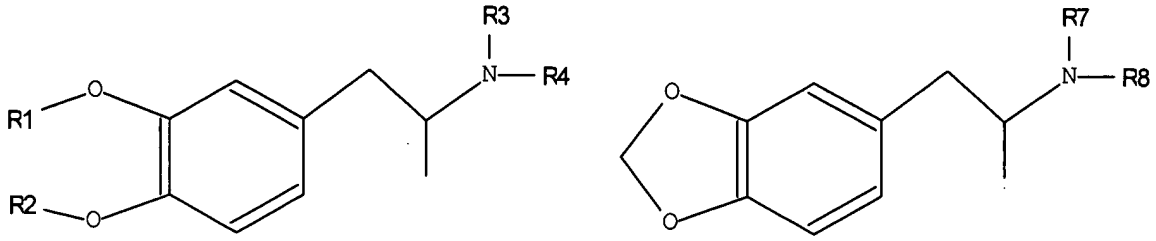
consisting of carbon, nitrogen, oxygen, sulfur wherein m>=1 and Z=moiety capable of bonding directly or indirectly with an immunogenic carrier or a detectable label (page 12, lines 1-3) or through a linking group (page 12 lines 9-11).

The detectable label may be a radioisotope, a fluorescent group, a luminescent group, enzyme etc. (page 5, lines 22-24; page 6, lines 1-10; page 9, lines 9-17; page 12, lines 10-15 and page 12, lines 12-14) and the carrier molecule may be protein, peptide etc. (page 13, lines 3-14; page 6, lines 1-10). Conjugation of the compound to solid particles is also disclosed (page 6, lines 14-18).

Rouhani discloses preparation of antibody (page 6, lines 19-24; pages 16-18) using the compound conjugated with carrier protein (see abstract) and different homogeneous and heterogeneous immunoassay methods (pages 8-9 and 34) and assay kit (page 31, lines 9-12 and claim 10) for detection and quantitation of ecstasy-class analogs in biological samples (page 22, lines19-24).

Rouhani also discloses the above compound conjugated with a protein to be adapted as immunogen (page 41, example 7). Attachment to a carrier protein or a label is also inherent in the process of immunization (see claims 7 and 8) and immunoassay methods (see pages 8-9 and 34) as disclosed in this reference.

The above disclosure reads on the compounds of formula I and II (claim 1 and 7):



wherein R1, R2= cycle; R3, R7=hydrogen or alkyl and R4 and R8 = as defined in claims 1 and 7.

Reference claims disclose immunogenic carrier, label, antibody, method and kit for immunoassay detection and quantitation of ecstasy compounds which anticipates all the cited claims of the instant invention.

Therefore, the reference is deemed to anticipate the cited claims.

Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 1-32 are provisionally rejected under the judicially created doctrine of double patenting over claims 1-37 of copending Application No. 10736005.

This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows:

Claims 1-37 of referenced patent are drawn to a compounds of formula I and II (claims 1 and 7) which anticipate formula I and II (claims 1 and 7) of the present. Referenced patent are also drawn to methods and kits comprising the same steps, ingredients and essentially the same composition as claimed in the cited claims of instant application.

15. Claims 1-24, 26, 28, 29 and 32 are provisionally rejected under the judicially created doctrine of double patenting over claims 1-20, 26-27, 29-30, 32-39, 49-53, 59-63, 66-67 and 69 of copending Application No. 10/736,018.

This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: the compounds

(formula I and formula II) of the reference claims when W is H and R_{19} and R_{20} are lower alkyl or taken together to form a ring and R_1, R_2 = H or lower alkyl reads on compound of formula I and II of the instant application. Reference claims disclose immunogenic carrier, label, antibody, method and kit for immunoassay detection and quantitation of ecstasy compounds which also anticipates cited claims of the instant invention. Compare, for example formula I of claim 1 of 10/736,004 wherein R^1, R^2, R^3, R^4=alkyl with formula I of claim1 of 10/736,018 wherein R_{19}, R_{20}, R_1, R_2=alkyl .

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Conclusion

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shafiqul Haq whose telephone number is 571-272-6103. The examiner can normally be reached on 7:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SHAFIQUL HAQ
EXAMINER
ART UNIT 1641

MARY E. CEPERLEY
PRIMARY EXAMINER
ART UNIT 1641